Research & Development

OSRAM
SYLVANIA

7 May, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-1170, Proposed Rules
Federal Register 9 February, 1999
Volume 64, Number 26, Pages 6288-6290

Gentlemen:

OSRAM SYLVANIA is part of a global lighting organization and is a major manufacturer of lamps and lighting products in North America. We produce ultraviolet emitting fluorescent lamps for photochemical, medical, and tanning applications and developed the original lamps and systems used in the PUVA treatment protocol. OSRAM SYLVANIA is the largest producer of sunlamps in North America and is the sole vertically integrated sunlamp manufacturer in North America with control over our own UV phosphor and glass technologies. Further, we are a supplier of lamp components to other sunlamp manufacturers. Because of our extensive experience in the design, development, and manufacture of UV lamps, we believe that we are highly qualified to comment on sunlamp products. In response to the subject notice, we offer the following comments on the proposed amendments to the performance standard for sunlamp products.

Comments Relative To Section II-4: Warning Information

We support the intent to simplify and update the current warning labelling on sunlamp products in order to improve communication of important information to the tanning salon patrons. Brevity and simplicity are desired to encourage reading and comprehension of warnings. We believe that the greatest impact is achieved when the warnings reflect consensus risk data based on generally accepted scientific and medical studies. Warnings located on components and their packaging, lamps for example, prevent inadvertent misuse, but users of tanning systems are unlikely to observe such warnings. The principal information needs to be on the external part of the tanning system where users can readily read it.

Comments Relative To Section II-6: Lamp Labeling and Compatibility

A. There is a need to address HID sunlamps and fluorescent sunlamps individually on some issues.

The original sunlamp regulations addressed both HID mercury sunlamps and fluorescent sunlamps simultaneously. With the expansion of the HID category to include a range of metal halide type lamps, the significant differences between fluorescent lamps and HID lamps become more important both in terms of lamp properties and of application methods. Large differences are possible in basic properties such as spectral characteristics, radiance, compactness, power levels, bulb operating temperature, hazards of physical lamp failure during operation, etc. These differences should be recognized. To this end we recommend that the two lamp types should be addressed separately when appropriate. Our comments herein will address issues applying to the fluorescent type sunlamp although some may apply equally well to the HID sunlamp.

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B. Requirements for sunlamps and requirements for tanning systems should be clearly differentiated.

In terms of photobiologically effective irradiance delivered to the tanning patron, the effect of a particular fluorescent lamp type depends on many factors. Examples of these are the number of lamps used, the physical arrangement of lamps in relation to the exposure location, the use of reflectors, the physical enclosure and protective equipment, the ballasts that operate the lamps, the ambient temperature at the lamps, etc. We recommend that the requirements applying to lamps and to tanning systems be more clearly differentiated. For example, current practice uses an exposure time as a lamp descriptor. Time as such is meaningless and may be misleading. The time to a specific endpoint using a given lamp can be significantly increased or decreased by the operating characteristics and design of a tanning system. Exposure guidance is a tanning system issue.

C. The C/B ratio characterization of fluorescent sunlamps should be eliminated.

HID sunlamps have the potential to produce high levels of UV-C (<260 nm), and this UV-C emission is controlled by integral and/or separate attenuating filters. However, the UV-C emission from fluorescent sunlamps is essentially due to traces of the 253.7 nm line emission produced by the internal, low pressure, mercury arc discharge. The high efficacy of a fluorescent lamp is caused by nearly complete absorption of this radiation by the lamp phosphor and its subsequent reemission at the desired longer wavelengths. The bulb wall glass effectively attenuates the small amount of this radiation that is not absorbed by the phosphor. Because traces that pass through both the phosphor and bulb are extremely small, their contribution to the wavelength integrated effective photobiological dose is negligible. Further, the C/B ratio is neither an indicator of safety nor effectiveness. Consequently, we recommend that the C/B ratio characterization be eliminated for fluorescent sunlamps. This does not increase the risk to tanning patrons. We observe that the carcinogenic risk at 253.7 nm is less than that in the UV-B [Sterenborg, van der Putte, & van der Leun, Photochem. Photobiol. 1988, 47:245; de Gruijl & van der Leun, Health Physics 1994, 67:319] and that the traces of 253.7 nm radiation still will be included in the erythemally weighted lamp emission to prevent an unintended erythemal effect.

D. The melanogenic characterization of lamps is redundant and should be eliminated.

The current lamp characterization using both erythemal and melanogenic criteria are correlated. These are not independent criteria due to the similarity of the weighting functions. A survey of many spectra over the range encountered with fluorescent ultraviolet and tanning lamps shows an extremely high correlation [$R^2 > 0.99$]. We recommend that only an erythemal characterization be used because erythema is the acute response that should limit exposure dose and is a criterion of exposure safety. Further, we propose that the CIE reference action spectrum for erythema of type I and II skin be used in accord with international recommendations in CIE Technical Report CIE 125-1997.

E. Lamp classification should be based on classification intervals commensurate with performance equivalence. The relevant parameters are erythemal effectiveness and UV-B to UV-A ratio.

We recommend that a lamp classification method using discrete steps be developed. It would be based on relevant lamp properties determined under standardized test conditions. The classification steps would be used to identify the proper lamp(s) for a tanning system and to identify lamps that are effectively equivalent. This would replace the present method involving a continuous scale of nominal exposure times. The objective is to more clearly identify compatibility of lamps and tanning systems and to avoid the potential of nontransitive equivalencies occurring if a variety of equivalent lamps evolve.

We are not proposing the details of a system but offer the following as a direction to be considered.

The erythemally effective irradiance would be determined at a designated point proximal to the center of the lamp length, the measurement that is made at the present. This would be done by spectroradiometry under specified and controlled lamp operating conditions. Present equivalency uses a consensus value of plus/minus 10 percent, and this suggests the size of acceptable steps along a rating scale. A logarithmic scale of weighted irradiance can be used to produce equally spaced steps of constant percentage difference. As an example, consider a criterion metric for 10 percent steps in the form: $24.16 \log_{10} (1000*E)$ rounded to the nearest integral value. The 24.16 multiplier adjusts the step size to 10 percent, and the 1000 multiplier adjusts the scale to all positive values. For example, a weighted irradiance of 0.134 W/m^2 would be in step 51 as determined by the equation. This system is open-ended and covers both present lamps and any future lamp development.

The reflectance of many metallic reflector materials and the transmittance of many plastic materials will start to decrease with decreasing wavelength in the mid UV-B. As a consequence, a tanning system has the potential to produce a greater difference between lamp and tanning system erythemal irradiance when the ratio of UV-B to UV-A is large than when it is small. Using lamps with similar B/A ratios would preserve the certification performance of a tanning system. We recommend using the concomitant designation of the B/A ratio to control this aspect. Again, a designation scale with discrete steps is necessary to identify and label functionally equivalent lamps. One way to accomplish this would be by designating the B/A ratio to the nearest 0.01.

Incorporating the B/A ratio in the lamp designation serves a second purpose. The consequences of exceeding one MED are more severe when the principal radiation is in the mid UV-B than in the UV-A [Hawk & Parrish in *The Science of Photomedicine*, Regan & Parrish ed., Plenum Press 1982]. Expectations of performance in a given tanning system will be influenced by past experience. If an inadvertent exposure exceeding one MED occurs, an uncontrolled change of B/A ratio could cause undesirable consequence.

The complete lamp designation would consist of two numbers, one on a discrete scale derived from benchmark irradiance and the other on a discrete scale using the B/A ratio; the form would be xx/yy. For example, if the lamp in the previous example with weighted irradiance of 0.134 W/m^2 had a B/A ratio of 0.038, the entire lamp classification would be 51/04. Any lamp with the same designation would be considered functionally identical. A tanning system would be certified for a specific lamp designation. Recertification would be required if another type of lamp were to be used in the system.

F. The effect of lamp maintenance characteristics should be reviewed.

Even under identical operating conditions (electrical and ambient), the output of a fluorescent lamp will slowly decrease over the time that the lamp is used. This gradual decrease in lamp output is a normal consequence of the physical processes within the lamp and is referred to as lamp maintenance. The rate of decrease is not the same for all lamps, but it is reasonably consistent for a given lamp type and mode of operation. We suggest that the consequences of this variation on the performance of tanning systems be reviewed.

The ratio of lamp emission after a specified operating time to the initial lamp emission is a simple but effective measure of lamp maintenance and known as the *maintenance factor*. If lamp maintenance variability between otherwise similar lamps types is found to have an adverse effect on safe and effective operation of tanning systems, the lamp maintenance factor can be used to differentiate between these types. A few ranges for maintenance factor could be designated, say I, II, and III. This would be appended as a third component of the lamp classification.

Comments Relative To Section II-3: Sunlamp Product Certification

We do not believe that a new classification scheme for fluorescent sunlamps will necessarily cause undue difficulties for existing tanning equipment. There are various options to avoid the need for extensive field recertification of existing tanning systems. As one example, a new lamp designation will be applied to existing sunlamp types as well as to future new types. A tanning system certified for an existing lamp type could then become certified for that lamp type in terms of the new lamp designation.

General Comment

We believe that it is necessary to have a basis for measurement quality included in the standard on sunlamp products. There is already a process in place for performance certification of laboratories in the lamp industry. We recommend that measurements be performed by a laboratory (or satellite of that laboratory) that is accredited for spectroradiometry under the National Voluntary Laboratory Accreditation Program (NVLAP) established in Title 15, Part 285, Code of Federal Regulations. The relevant Scope of Accreditation would include IES LM-55 *IESNA Guide for the Measurement of Ultraviolet Radiation from Sources*, IES LM-58 *IESNA Guide to Spectroradiometric Measurements*, and ANSI/IESNA RP-27.2-xx *Recommended Practice for Photobiological Safety of Lamps and Lamp Systems - Measurement Techniques* (in approval process).

Very truly yours,

Robert E. Levin, Ph.D.
Corporate Scientist

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